



This is provisional English translation of an excerpt from the original full report.

Safety Assessment Report

Oilseed rape MS11 line

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

October 2019

ABSTRACT

FSCJ conducted a safety assessment of oilseed rape, MS11 line male sterile and tolerant of glufosinate herbicide, based on the documents submitted by the applicant.

Oilseed rape MS11 line was generated through the introduction of the modified Phosphinothricin acetyltransferase (PAT) gene derived from *Streptomyces hygroscopicus*. This gene insertion results in the expression of the modified PAT protein, thus the oilseed rape MS11 line becomes tolerant of glufosinate herbicides. Modified *baranase* gene derived from *Bacillus amyloliquefaciens* encoding modified BARNASE protein expresses the modified BARNASE protein, a ribonuclease, in the tapet cells of anther under the action of anther-specific promoter Pta29. Consequently, the protein inhibits pollen formation through decomposition of the RNA in the tapet cells during anther formation, thus the oilseed rape MS11 line becomes male sterile. In addition, *barstar* gene encoding BARSTAR protein derived from *B. amyloliquefaciens* was introduced by Agrobacterium method for the purpose of improvement of transformation efficiency.

Safety of the inserted genes, toxicity and allergenicity of the proteins produced from the inserted genes, sequence of the genes after the insertion, stability of the inserted genes in the successive generations, influences on metabolic pathways in the plant, and nutrients and toxic ingredients in the plant were evaluated based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”¹. None of newly generated safety concerns was detected in comparison with oilseed rape line without genetic modification.

Consequently, FSCJ concluded that oilseed rape MS11 line male sterile and tolerant of glufosinate herbicide, has no concern relevant to human health.

¹ “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)” (Decision of the Commission dated 29 January 2004)